UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,289	10/09/2003	F. Barry Bays	702.113	9339

37902 7590 04/15/2009
WRIGHT MEDICAL TECHNOLOGY, INC.
LEGAL DEPARTMENT
5677 AIRLINE ROAD
ARLINGTON, TN 38002-9501

EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
04/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/682,289
Filing Date: October 09, 2003
Appellant(s): BAYS ET AL.

Shawn D. Sentilles
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed June 10, 2008 appealing from the Office action mailed January 11, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,723,131	Muschler	04-2004
2003/0180262	Wironen et. al.	09-2003
6,736,799	Erbe et. al.	05-2004
4,846,174	Willard et. al.	07-1989

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 23 – 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muschler (US 6723131) in view of Wironen et al. (US 2003/0180262 A1).

Appellant claims an apparatus for preparing a bone graft composite comprising a tube with a first and second end; a first removable end cap which allows passage of bone marrow aspirate delivery member and attachment to a bone marrow aspirate delivery member; a second removable end cap which allows communication between the tube and a filter and is configured to attach with a filter; a removable filter membrane attached to the second end cap; a filter in the membrane that prevents bone marrow aspirate to flow through while allowing air to flow through; and a bone graft in the tube. The graft material is selected from calcium sulfate, calcium phosphate, tri-calcium phosphate, hydroxyapatite, coral hydroxyapatite, demineralized bone matrix, and mineralized bone matrix, specifically tri-calcium phosphate; the bone graft material is porous to bone marrow aspirate; or the bone graft material comprises a plurality of small bone pieces. The end caps and filter membranes have removable sealing caps, wherein a second sealing cap provides an air tight environment; and washers are disposed between the end caps and tube ends. The apparatus further comprises bone marrow aspirate that is introduced via the first end and having had air expelled through the filter; the bone marrow aspirate is allowed to coagulate in the tube after contact with the bone graft material; and the bone graft material is substantially saturated with the aspirate. The first end cap is configured for attachment to a syringe.

Muschler teaches an apparatus for preparing a bone graft composite (abstract), the apparatus comprising a tube with a first and second end (figures), removable end caps (col.7 line 11-14) that may allow for passage of a syringe (or a bone marrow aspirate delivery member) (col.7 line 25-30) or attachment to a screen (or filter) membranes (or end caps that allow communication with filters and bone marrow aspirate delivery members) (col.7 line 15-19); and a bone graft material therein (col.6 line 59-64). The bone graft material may be calcium phosphate, tri-calcium phosphate, hydroxyapatite, coral hydroxyapatite, demineralized bone matrix, and mineralized bone matrix (col.4 line 13-55); is porous to marrow aspirate (col.4 line 13-15, col.3 line 38-45); or may comprise a plurality of small bone pieces (col.4 line 50-col.5 line 20). The bone marrow aspirate is not anticoagulated, but is allowed to clot (or coagulate) during mixing (or substantially saturating) with the graft material (or within the tube) (col.8 line 51-54).

Muschler does not teach the apparatus wherein the filter membrane prevents aspirate passage while allowing air to pass through. However, Wironen teaches apparatuses for making bone graft composites (abstract, figures), wherein one end has a filter membrane attached to prevent passage of bone paste components (or aspirate and/or graft materials) while expelling air from the tube (0045). Wironen teaches that it is desirable to remove air from the paste components before, during or after reconstitution is conducted (0045). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use the filter of Wironen in the apparatus of Muschler for the disclosed desirability for removing air from the bone graft composite material during mixing (0045). Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Wironen to use a filter that prevents passage of bone paste components (or aspirate and/or graft materials) while expelling air with a reasonable expectation for successfully obtaining an apparatus for making bone graft composites.

The combined teachings of the references do not specifically teach the apparatus wherein the aspirate is introduced via a first end having air expelled through the filter of the second end. However Muschler does teach the aspirate being loaded via the first end by means known in the art (col.7 line 39-46), and that the second end may contain a filter membrane. Further, Wironen teaches the advantages of using membranes that prevent passage of aspirate while allowing air to pass through (0045). Thus, the combined teachings of Muschler and Wironen clearly suggest to one of ordinary skill in the art to load the tube through one end while expelling air through the other.

The references do not teach the apparatus wherein the end caps have removable sealing caps, or wherein washers are used between the tube and end caps. However, in the response filed on March 14, 2006 to the restriction requirement mailed on February 14, 2006, Appellant clearly admitted on the record that the groups of the various inventions were obvious over each other under the meaning of 35 USC 103. Specifically, in that the inventions of a bone graft material, methods for making the material and the claimed apparatus for holding or preparing the bone graft material are obvious over each other under the meaning of 35 USC 103. Standard examination practice dictates that when an applicant traverses restrictions on the grounds that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence of record showing the inventions to be obvious variants **or** clearly admit on the record that this is the case. Furthermore, in either case, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions. This practice has long been established and is further supported by the MPEP (form paragraph 8.21). In the instant application, Appellant clearly admitted on the record that the inventions were obvious variants over each other. Although the instant claims were not presented in the original restriction requirement, the instant claims are drawn to the same invention of original group I, and have been prosecuted as such throughout the history of the instant application. Thus, in finding the inventions of a bone graft material, methods for making the material and an apparatus for housing/preparing the material, those inventions and/or limitations not specifically disclosed by the art are rendered obvious under 35 USC 103, as admitted by Appellant. While claims to the bone graft and methods for making the graft have been canceled, Appellant's earlier admission remains applicable over limitations of the apparatus not disclosed by the cited art. Therefore, while the references do not teach the apparatus with removable sealing caps and washers, the limitations are rendered obvious.

Claims 23 – 29, 32 and 35 – 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muschler in view of Wironen and further in view of Erbe et al. (US 6736799 B1).

Appellant claims an apparatus for preparing a bone graft composite comprising a tube with a first and second end; a first removable end cap which allows passage of bone marrow aspirate delivery member and attachment to a bone marrow aspirate delivery member; a second removable end cap which allows communication between the tube and a filter and is configured to attach with a filter; a removable filter membrane attached to the second end cap; a filter in the membrane that prevents bone marrow aspirate to flow through while allowing air to flow through; and a bone graft in the tube. The graft material is selected from calcium sulfate, calcium phosphate, tri-calcium phosphate, hydroxyapatite, coral hydroxyapatite, demineralized bone matrix, and mineralized bone matrix, specifically tri-calcium phosphate; the bone graft material is porous to bone marrow aspirate; or the bone graft material comprises a plurality of small bone pieces. The end caps and filter membranes have removable sealing caps, wherein a second sealing cap provides an air tight environment. The apparatus further comprises bone marrow aspirate that is introduced via the first end and having had air expelled through the filter; the bone marrow aspirate is allowed to coagulate in the tube after contact with the bone graft material; and the bone graft material is substantially saturated with the aspirate. The first end cap is configured for attachment to a syringe.

Muschler teaches an apparatus for preparing a bone graft composite (abstract), the apparatus comprising a tube with a first and second end (figures), removable end caps (col.7 line 11-14) that may allow for passage of a syringe (or a bone marrow aspirate delivery member) (col.7 line 25-30) or attachment to a screen (or filter) membranes (or end caps that allow communication with filters and bone marrow aspirate delivery members) (col.7 line 15-19); and a bone graft material therein (col.6 line 59-64). The bone graft material may be calcium phosphate, tri-calcium phosphate, hydroxyapatite, coral hydroxyapatite, demineralized bone matrix, and mineralized bone matrix (col.4 line 13-55); is porous to marrow aspirate (col.4 line 13-15, col.3 line 38-45); or may comprise a plurality of small bone pieces (col.4 line 50-col.5 line 20). The bone marrow aspirate is not anticoagulated, but is allowed to clot (or coagulate) during mixing (or substantially saturating) with the graft material (or within the tube) (col.8 line 51-54).

Muschler does not teach the apparatus wherein the filter membrane prevents aspirate passage while allowing air to pass through. However, Wironen teaches apparatuses for making bone graft composites (abstract, figures), wherein one end has a filter membrane attached to prevent passage of bone paste components (or aspirate and/or graft materials) while expelling air from the tube (0045). Wironen teaches that it is desirable to remove air from the paste components before, during or after reconstitution is conducted (0045). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use the filter of Wironen in the apparatus of Muschler for the disclosed desirability for removing air from the bone graft composite material during mixing (0045). Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Wironen to use a filter that prevents passage of bone paste components (or aspirate and/or graft materials) while expelling air with a reasonable expectation for successfully obtaining an apparatus for making bone graft composites.

The combined teachings of the references do not specifically teach the apparatus wherein the aspirate is introduced via a first end having air expelled through the filter of the second end. However Muschler does teach the aspirate being loaded via the first end by means known in the art (col.7 line 39-46), and that the second end may contain a filter membrane. Further, Wironen teaches the advantages of using membranes that prevent passage of aspirate while allowing air to pass through (0045). Thus, the combined teachings of Muschler and Wironen clearly suggest to one of ordinary skill in the art to load the tube through one end while expelling air through the other.

The references do not teach the apparatus wherein the end caps have removable sealing caps. However, at the time of the claimed invention, the end caps of apparatuses for making bone graft composites were commonly sealed in the art. In support, Erbe teaches an apparatus for making bone composite materials wherein the end caps are closed (or sealed) to seal the material chamber (or tube with graft material) (col.3 line 9-25, claims). While the reference does not expressly teach the sealing cap in addition to the end cap, the reference certainly suggests to one in the art the desire to seal the graft tubes. Thus, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by common practice, as evidenced by Erbe, to include a sealing cap on the apparatus of Muschler with a reasonable expectation for successfully obtaining an apparatus effective to prepare a bone graft composite.

Claims 23 – 27, 30 – 33, 36 – 38 and 40 - 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muschler in view of Wironen and further in view of Willard et al. (US 4846174).

Appellant claims an apparatus for preparing a bone graft composite comprising a tube with a first and second end; a first removable end cap which allows passage of bone marrow aspirate delivery member and attachment to a bone marrow aspirate delivery member; a second removable end cap which allows communication between the tube and a filter and is configured to attach with a filter; a removable filter membrane attached to the second end cap; a filter in the membrane that prevents bone marrow aspirate to flow through while allowing air to flow through; and a bone graft in the tube. The graft material is selected from calcium sulfate, calcium phosphate, tri-calcium phosphate, hydroxyapatite, coral hydroxyapatite, demineralized bone matrix, and mineralized bone matrix, specifically tri-calcium phosphate; the bone graft material is porous to bone marrow aspirate; or the bone graft material comprises a plurality of small bone pieces. Washers are disposed between the end caps and tube ends. The apparatus further comprises bone marrow aspirate that is introduced via the first end and having had air expelled through the filter; the bone marrow aspirate is allowed to coagulate in the tube after contact with the bone graft material; and the bone graft material is substantially saturated with the aspirate. The first end cap is configured for attachment to a syringe.

Muschler teaches an apparatus for preparing a bone graft composite (abstract), the apparatus comprising a tube with a first and second end (figures), removable end caps (col.7 line 11-14) that may allow for passage of a syringe (or a bone marrow aspirate delivery member) (col.7 line 25-30) or attachment to a screen (or filter) membranes (or end caps that allow communication with filters and bone marrow aspirate delivery members) (col.7 line 15-19); and a bone graft material therein (col.6 line 59-64). The bone graft material may be calcium phosphate, tri-calcium phosphate, hydroxyapatite, coral hydroxyapatite, demineralized bone matrix, and mineralized bone matrix (col.4 line 13-55); is porous to marrow aspirate (col.4 line 13-15, col.3 line 38-45); or may comprise a plurality of small bone pieces (col.4 line 50-col.5 line 20). The bone marrow aspirate is not anticoagulated, but is allowed to clot (or coagulate) during mixing (or substantially saturating) with the graft material (or within the tube) (col.8 line 51-54).

Muschler does not teach the apparatus wherein the filter membrane prevents aspirate passage while allowing air to pass through. However, Wironen teaches apparatuses for making bone graft composites (abstract, figures), wherein one end has a filter membrane attached to prevent passage of bone paste components (or aspirate and/or graft materials) while expelling air from the tube (0045). Wironen teaches that it is desirable to remove air from the paste components before, during or after reconstitution is conducted (0045). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use the filter of Wironen in the apparatus of Muschler for the disclosed desirability for removing air from the bone graft composite material during mixing (0045). Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Wironen to use a filter that prevents passage of bone paste components (or aspirate and/or graft materials) while expelling air with a reasonable expectation for successfully obtaining an apparatus for making bone graft composites.

The combined teachings of the references do not specifically teach the apparatus wherein the aspirate is introduced via a first end having air expelled through the filter of the second end. However Muschler does teach the aspirate being loaded via the first end by means known in the art (col.7 line 39-46), and that the second end may contain a filter membrane. Further, Wironen teaches the advantages of using membranes that prevent passage of aspirate while allowing air to pass through (0045). Thus, the combined teachings of Muschler and Wironen clearly suggest to one in the art to load the tube through one end while expelling air through the other.

The references do not teach the apparatus wherein washers are used between the tube and end caps. However, Muschler teaches that the end caps are removable to the tube via threaded connections, or any other known connection (col.7 line 12-14). At the time of the claimed invention, it was known to include washers between caps and threaded connections for their aid in equalizing pressure distribution, securing placement and ensuring air tightness. In support, Willard teaches columnar tubes wherein a threaded end has a removable cap and washer placed in between to secure the assembly (col.11 line 55-col.12 line 14, figure 1). Thus, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by common practice, as evidenced by Willard, to include a washer in the apparatus of Muschler with a reasonable expectation for successfully obtaining an apparatus effective to prepare a bone graft composite.

Claims 23 – 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muschler in view of Wironen and further in view of Erbe and Willard.

Appellant claims an apparatus for preparing a bone graft composite comprising a tube with a first and second end; a first removable end cap which allows passage of bone marrow aspirate delivery member and attachment to a bone marrow aspirate delivery member; a second removable end cap which allows communication between the tube and a filter and is configured to attach with a filter; a removable filter membrane attached to the second end cap; a filter in the membrane that prevents bone marrow aspirate to flow through while allowing air to flow through; and a bone graft in the tube. The graft material is selected from calcium sulfate, calcium phosphate, tri-calcium phosphate, hydroxyapatite, coral hydroxyapatite, demineralized bone matrix, and mineralized bone matrix, specifically tri-calcium phosphate; the bone graft material is porous to bone marrow aspirate; or the bone graft material comprises a plurality of small bone pieces. The end caps and filter membranes have removable sealing caps, wherein a second sealing cap provides an air tight environment; and washers are disposed between the end caps and tube ends. The apparatus further comprises bone marrow aspirate that is introduced via the first end and having had air expelled through the filter; the bone marrow aspirate is allowed to coagulate in the tube after contact with the bone graft material; and the bone graft material is substantially saturated with the aspirate. The first end cap is configured for attachment to a syringe.

Muschler teaches an apparatus for preparing a bone graft composite (abstract), the apparatus comprising a tube with a first and second end (figures), removable end caps (col.7 line 11-14) that may allow for passage of a syringe (or a bone marrow aspirate delivery member) (col.7 line 25-30) or attachment to a screen (or filter) membranes (or end caps that allow communication with filters and bone marrow aspirate delivery members) (col.7 line 15-19); and a bone graft material therein (col.6 line 59-64). The bone graft material may be calcium phosphate, tri-calcium phosphate, hydroxyapatite, coral hydroxyapatite, demineralized bone matrix, and mineralized bone matrix (col.4 line 13-55); is porous to marrow aspirate (col.4 line 13-15, col.3 line 38-45); or may comprise a plurality of small bone pieces (col.4 line 50-col.5 line 20). The bone marrow aspirate is not anticoagulated, but is allowed to clot (or coagulate) during mixing (or substantially saturating) with the graft material (or within the tube) (col.8 line 51-54).

Muschler does not teach the apparatus wherein the filter membrane prevents aspirate passage while allowing air to pass through. However, Wironen teaches apparatuses for making bone graft composites (abstract, figures), wherein one end has a filter membrane attached to prevent passage of bone paste components (or aspirate and/or graft materials) while expelling air from the tube (0045). Wironen teaches that it is desirable to remove air from the paste components before, during or after reconstitution is conducted (0045). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use the filter of Wironen in the apparatus of Muschler for the disclosed desirability for removing air from the bone graft composite material during mixing (0045). Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Wironen to use a filter that prevents passage of bone paste components (or aspirate and/or graft materials) while expelling air with a reasonable expectation for successfully obtaining an apparatus for making bone graft composites.

The combined teachings of the references do not specifically teach the apparatus wherein the aspirate is introduced via a first end having air expelled through the filter of the second end. However Muschler does teach the aspirate being loaded via the first end by means known in the art (col.7 line 39-46), and that the second end may contain a filter membrane. Further, Wironen teaches the advantages of using membranes that prevent passage of aspirate while allowing air to pass through (0045). Thus, the combined teachings of Muschler and Wironen clearly suggest to one of ordinary skill in the art to load the tube through one end while expelling air through the other.

The references do not teach the apparatus wherein the end caps have removable sealing caps or wherein washers are used between the tube and end caps. However, at the time of the claimed invention, the end caps of apparatuses for making bone graft composites were commonly sealed in the art. In support, Erbe teaches an apparatus for making bone composite materials wherein the end caps are closed (or sealed) to seal the material chamber (or tube with graft material) (col.3 line 9-25, claims). While the reference does not expressly teach the sealing cap in addition to the end cap, the reference certainly suggests to one in the art the desire to seal the graft tubes. Thus, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by common practice, as evidenced by Erbe, to include a sealing cap on the apparatus of Muschler with a reasonable expectation for successfully obtaining an apparatus effective to prepare a bone graft composite. In addition, it was further known to include washers between caps and threaded connections for their aid in equalizing pressure distribution, securing placement and ensuring air tightness. In support, Willard teaches columnar tubes wherein a threaded end has a removable cap and washer placed in between to secure the assembly (col.11

line 55-col.12 line 14, figure 1). Thus, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by common practice, as evidenced by Willard, to include a washer in the apparatus of Muschler with a reasonable expectation for successfully obtaining an apparatus effective to prepare a bone graft composite.

(10) Response to Argument

Appellant argues that the references do not teach all of the claimed features such as a filter membrane removably coupled to the leading end of the second end cap, a filter in the filter membrane which prevents bone marrow aspirate passage while allowing air to pass through, and the presence of bone marrow aspirate and bone graft materials in the tube. Appellant further argues that the combination destroys the teachings of Muschler; that Muschler teaches away from removing air, but allows aspirate to pass; that Muschler teaches an optional membrane to retain the mixture within the tube. Appellant argues that Wironen teaches preserving bone pastes, not preparing bone marrow aspirate; that removing air is not disclosed but removal of air bubbles. Appellant argues that the admission under 35 USC 103 was in response to a restriction requirement and not an admission that the groups were obvious over each other. Appellant further states that a proper determination of obviousness has not been made; that the admission was a concession to the restriction requirement where the examiner did not establish that the groups were independent and distinct; that a proper showing of distinctness was not made; and that the claims of the restriction have since been canceled in favor of apparatus claims. Appellant asserts that the examiner’s position is unclear regarding the admission and has not provided a sufficient explanation such that Appellant may properly respond. Finally Appellant argues the examiner applies improper hindsight.

However, these arguments fail to persuade for the following reasons.

Regarding Appellant's argument that the references do not teach all of the claimed elements, it is noted that the combination of references teach and suggest various filters, membranes, couplings, seals, end caps, washers and presence of aspirate and bone graft materials for use in apparatuses for preparing bone graft materials as evidenced by the rejections above.

Regarding Appellant's assertions that the combination destroys the function of Muschler, it is noted that the rejection is based on a combination of references. The combination of references suggests to one in the art that air removal is advantageous before, during or after reconstitution of bone pastes (or bone graft materials). It is maintained that the teachings of Wironen suggest to one in the art that it is advantageous to remove air before, during or after reconstitution of bone pastes (or bone graft materials). Wironen specifically teaches apparatuses for making bone graft composites (abstract, figures), wherein one end has a filter membrane attached to prevent passage of bone paste components (or aspirate and/or graft materials) while expelling air from the tube (0045), thereby teaching a filter that allows air to pass and not bone graft materials, or BMA. Thus, the combination of Muschler and Wironen suggest to one of ordinary skill in the art that it is desirable to remove air from the bone graft composite material during mixing (0045). Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Wironen to use a filter that prevents passage of bone paste components (or aspirate and/or graft materials) while expelling air with a reasonable expectation for successfully obtaining an apparatus for making bone graft composites.

Regarding the asserted teaching away from the claimed invention, it is noted that Muschler neither teaches that air should be retained in the BMA, nor that air is beneficial to the cell population. Thus, the reference does not have a specific teaching away from air removal. Furthermore, the combined teachings of Muschler and Wironen suggest that air removal is desirable and that a filter to allow air passage and not BMA would benefit the apparatus of Muschler.

Regarding the optional membrane to allow aspirate to remain in the tube, it is maintained that the teaching of Muschler is clear that such a membrane may in incorporated into the apparatus. Moreover, such a filter membrane is suggested by the prior art.

Regarding the teachings of Wironen, the reference specifically teaches air bubbles (or air) should be expelled, or that air is removed, from the bone graft materials, or BMA (0045). Furthermore, the reference is relied upon to evidence the need for removal of air, and in turn a filter for allowing air to pass without allowing BMA to pass from the apparatus of Muschler.

Regarding Appellant's arguments to the previous admission by Appellant, it is reiterated that in the response filed on March 14, 2006 to the restriction requirement mailed on February 14, 2006, Appellant clearly admitted on the record that the groups of the various inventions were obvious over each other under the meaning of 35 USC 103. Specifically, in that the inventions of a bone graft material, methods for making the material and the claimed apparatus for holding or preparing the bone graft material are obvious over each other under the meaning of 35 USC 103. Standard examination practice dictates that when an applicant traverses restrictions on the grounds that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence of record showing the inventions to be obvious variants **or** clearly admit on the record that this is the case. Furthermore, in either case, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions. This practice has long been established and is further supported by the MPEP (form paragraph 8.21). In the instant application, Appellant clearly admitted on the record that the inventions were obvious variants over each other (See response filed on 3/14/2006). Although the instant claims were not presented in the original restriction requirement, the instant claims are drawn to the same invention of original group I (an apparatus for preparing a bone graft), and have been prosecuted as such throughout the history of the instant application. It is noted that if the instant claims were not considered to be the same invention as the originally presented claims 1 – 7, then the instant claims would not have been entered and an election by original presentation requirement would have been made (thereby requiring Appellant to cancel the instant claims and prosecute the original claims set). Since the Examiner clearly considered the instant claims drawn to the invention presented in group I, the claims have been properly considered and prosecuted as such. Thus, in finding the inventions of a bone graft material, methods for making the material and an apparatus for housing/preparing the material, those inventions and/or limitations not specifically disclosed by the art are rendered obvious under 35 USC 103, as admitted by Appellant. While claims to the bone graft and methods for making the graft have been canceled, Appellant's earlier admission remains applicable over limitations of the apparatus not disclosed by the cited art. Therefore, while the references do not teach the apparatus with removable sealing caps and washers, the limitations are rendered obvious. Regarding the assertion that a proper distinction was not made between the groups, it is noted that the original restriction requirement clearly set forth other materially different apparatuses which could be used to practice the methods and other methods by which bone grafts could be made. Furthermore, all of the groups were shown to exhibit distinctness, to include groups I:III, I:V and IV:V (see Office Action mailed on 2/14/2006: p.2 para 2, p.2 para 2, and p.3 para 3, respectively). Finally, it is maintained that the Examiner has properly and clearly set forth the reasons and rationale behind the application of 35 USC 103(a) in response to Appellant's admission under 35 USC 103.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Ruth A Davis

/Ruth A. Davis/

Primary Examiner, Art Unit 1651

Conferees:

/Michael G. Wityshyn/

Supervisory Patent Examiner, Art Unit 1651

/Cecilia Tsang/

Supervisory Patent Examiner, Art Unit 1654